



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/532,682

04/26/2005

Hideo Kawachi

5404/101

8726

757 7590 03/03/2009
BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER

WEBB, WALTER E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

03/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,682	Applicant(s) KAWACHI, HIDEO	
	Examiner WALTER E. WEBB	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 11/26/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

Claims 6 and 7 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that "crystallinity" is **obtained** by measuring the water content of hydration in the aggregate using thermogravimetric analysis. However, this is incorrect. Crystallinity is *determined* not obtained by thermogravimetric analysis. Thermogravimetric analysis is a type of testing that is performed on samples to determine changes in weight in relation to change in temperature, it does not effect the sample. "Crystallinity" is **obtained** from the precipitation process. The crystallinity percentage indicates of how much of the ergosterol is crystallized from the crude solution. Applicant has not overcome this rejection by amending the claims to recite the phrase "wherein the crystallinity is an amount of crystal component in the aggregate by measuring water of hydration by thermogravimetric analysis."

Claim Rejections - 35 USC § 102--previous

Claims 1, 3, 6 and 7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bills (US 1,842,929). This rejection also applies to newly added **claim 8**.

Applicant argues that Bills does not disclose using water-insoluble organic solvent in the removing step. However, Bills teaches a method of preparing ergosterol, where ergosterol is extracted from saponification of yeast fat. (See col. 1, lines 37-40, and col. 2, lines 65-92.) The yeast fat suffices here as a water insoluble organic solvent.

Applicant argues that neither Bills nor the divisional Patent 1,755,548 disclose adding water to the water-insoluble organic solvent. However, Bills teaches that water is added to the saponification mixture to precipitate ergosterol. (See *ibid.*) The amount of water is controlled insofar as the water was added to such an extent as not to incomplete precipitation, as per claim 2. (See col. 2, lines 78-87.)

In regard to claims 6 and 7, determining crystallinity by thermogravimetric analysis is not a step in the process of separating ergosterol, but a way to measure changes in weight in relation to change in temperature to figure the crystal content of the precipitate. Since the method of Bills results in 60% crystal ergosterol, it satisfies a crystallinity of 50% to 90% as per claims 6 and 7.

In regard to claim 8, the reference teaches ergosterol precipitation by a cooling crystallization insofar as the purification process of the '548 patent teaches that the crystals were obtained once the solution was cooled to 0°C (see US 1,775,548, col. 2, lines 90-92).

Claim Rejections - 35 USC § 103—previous

1) Claims 1, 3, 4, 6, and 7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Knol (*previous*) in view of Bills (*supra*). This rejection also applies to newly added **claim 8**.

In regard to claim 8, Knol teaches ergosterol precipitation by a cooling crystallization insofar as it teaches a cooling step in the process to generate the ergosterol crystals (see col. 6, line 75.)

Knol, taught previously, differs from the instant claim 1 insofar as it is silent as to the phase separation between the water-insoluble organic solvent and water.

Applicant argues that a skilled artisan would not have motivation, or any reasonable expectation of success, to control water in a very small amount because both decomposition and the extraction require a certain amount of water. However, applicant's have not claimed a certain amount of water. It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to adjust the water such that no phase separation occurs, motivated by the teaching of Bills that success of precipitation of ergosterol depends on the correct amount of water (see col. 2, lines 78-87.) Bills teaches that too much water will hold the ergosterol partly in colloidal suspension, while too little water will cause incomplete precipitation. (See *ibid.*) This is consistent with applicant's disclosure where it states, "If the amount of water is too large, the water-insoluble organic solvent solution is separated into two

Art Unit: 1612

liquid phases, a water-insoluble organic solvent phase and a water phase. As a result, it becomes difficult to handle" (See Specification at pg. 7, lines 12-15.)

Applicant argues that Bills uses a relatively large amount of water and that the artisan would readily know that the mixture would be separated into two phases when the same amount of water called for in Bills is added to the water-insoluble solvent described in Knol. However, applicant provides no evidence or scientific basis for this conclusion. Since Bills cautions that adding too much water would hold the ergosterol partly in colloidal suspension, the artisan would adjust the amount of water added to prevent the colloidal suspension of ergosterol.

Applicant states that the product of Bills has poor solid-liquid separation, but provides no evidence to support this conclusion. There is no indication given in Bills that the product has poor solid-liquid separation characteristics.

2) Claim 5 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Knol (*supra*) as applied to claims 1, 3, 4, 6, and 7 above, in view of Bills (*supra*) and in further view of Nimberger et al., (US 5,498,138).

Applicant argues that Nimberger et al. does not disclose or suggest that the sampling pump is suitable or is used for supplying water in precipitation process of an organic compound such as ergosterol. However, it would have been obvious to use the fluid regulator of Nimberger et al. to ensure that the right amount of water is used for the precipitation of ergosterol from the organic solution of Knol. Such a device would be useful in an apparatus for mass production of ergosterol.

3) Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bills (*supra*) as applied to claims 1, 3, 6 and 7 above, in view of Nimberger et al., (US 5,498,138).

Applicant argues that the refereces to not disclose or suggest that the amount of water supplied is very small. However, applicant does not claim that the amount of water supplied is very small.

Applicant also argues that Bills does not disclose or suggest that water is supplied by moisturizing a gas phase portion in a system for precipitating ergosterol. However, it would have been obvious to use the fluid regulator of Nimberger et al. to ensure that the right amount of water is used for the precipitation of ergosterol from the organic solution of Bills. Such a device would be useful in an apparatus for mass production of ergosterol.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1612

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WALTER E. WEBB whose telephone number is (571)270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

Application/Control Number: 10/532,682

Page 8

Art Unit: 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612